line: Live Microbiome-Based Products Workshop).

SUPPLEMENTARY INFORMATION:

I. Background

Live microbiome-based products used to prevent, treat, or cure a disease or condition in humans are biological products. There is increasing interest in the use of such products for the treatment and/or prevention of conditions such as necrotizing enterocolitis and diarrhea. Historically, these products have presented with unique scientific and regulatory challenges.

II. Topics for Discussion at the Public Workshop

The topics for discussion at the public workshop include the clinical, manufacturing, and regulatory considerations for live microbiome-based products to prevent, treat, or cure a disease or condition in humans, and the objective is to provide a forum for the exchange of information and perspectives on these topics.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://www.eventbrite.com/e/science-and-regulation-of-live-microbiome-based-products-used-to-prevent-treat-or-cure-diseases-in-tickets-44649072578.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by August 28, 2018, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Loni Warren Henderson or Sherri Revell no later than September 10, 2018 (See **FOR FURTHER INFORMATION CONTACT**).

Dated: August 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17732 Filed 8–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1592]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Controlled Correspondence Related to Generic Drug Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 17, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0797. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10a.m.–12 midnight, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Controlled Correspondence Related to Generic Drug Development

OMB Control Number 0910–0797—Extension

This information collection supports the above captioned Agency guidance. FDA has agreed to specific program enhancements and performance goals specified in the Generic Drug User Fee Reauthorization (GDUFA II) Commitment Letter. One of the performance goals applies to controlled correspondence related to generic drug development. The GDUFA II Commitment Letter includes details on FDA's commitment to respond to questions submitted as controlled correspondence within certain timeframes. To support these program goals, we have developed the guidance entitled ''Controlled Correspondence Related to Generic Drug Development.'' The guidance document is intended to facilitate FDA's prompt consideration of controlled correspondence and to assist in meeting the prescribed timeframes by providing procedural recommendations to include the following information in the inquiry: (1) Name, title, address, phone number, and entity of the person submitting the inquiry; (2) a letter of authorization, if applicable; (3) the FDA-assigned control number and submission date of any previous, related controlled correspondence that was accepted for substantial review and response, if any, as well as a copy of that previous controlled correspondence and FDA's response, if any; (4) the relevant reference listed drug(s), as applicable, including the application number, proprietary (brand) name, manufacturer, active ingredient, dosage form, and strength(s); (5) a statement that the controlled correspondence is related to a potential abbreviated new drug application (ANDA) submission to the Office of Generic Drugs and the ANDA number, if applicable; (6) a concise statement of the inquiry; (7) a recommendation of the appropriate FDA review discipline; and (8) relevant prior research and supporting materials.

The GDUFA II Commitment Letter also includes details on FDA's commitment to respond to requests to clarify ambiguities in FDA's controlled correspondence response within certain timeframes. To facilitate FDA's prompt consideration of the request and to assist in meeting the prescribed timeframes, the guidance document recommends including the following information in the inquiry: (1) Name, title, address, phone number, and entity of the person submitting the inquiry; (2) a letter of authorization, if applicable; (3) the FDA-assigned control number, submission date of the controlled correspondence on which the requestor is seeking clarification, a copy of that previous controlled correspondence, and FDA's response to the controlled correspondence; and (4) the clarifying questions and the corresponding section(s) of FDA's controlled correspondence response on which the requestor is seeking clarification.

In the **Federal Register** of May 22, 2018, (83 FR 23692), we published a 60-day notice requesting public comment on the proposed collection of

information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Submission of controlled correspondence	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Generic drug manufacturers, related industry, and representatives	390	3.8	1,496	5	7,480

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This is the first extension of the information collection. We base our estimate on a review of Agency data of Fiscal Year submissions for 2014, 2015, and 2016, which reflects an increase in submissions that we attribute to an increase in generic drug development. Accordingly, we estimate 390 generic drug manufacturers and related industry (*e.g.,* contract research organizations conducting bioanalytical or bioequivalence clinical trials) or their representatives will each submit an average of 3.8 inquiries annually for a total of 1,496 inquiries [1,496 ÷ 390 = 3.8]. Information submitted with each inquiry varies widely in content, depending on the complexity of the request. Inquiries that are defined as controlled correspondence may range from a simple inquiry on generic drug labeling to a more complex inquiry for a formulation assessment for a specific proposed generic drug product. As a result, these inquiries can vary between 1 and 10 burden hours.

Because the content of inquiries considered controlled correspondence is widely varied, we are providing an average burden hour for each inquiry. We estimate that it will take an average of 5 hours per inquiry for industry to gather necessary information, prepare the request, and submit the request to FDA. As a result, we estimate that it will take an average of 7,480 hours annually for industry to prepare and submit inquiries considered controlled correspondence.

Dated: August 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17787 Filed 8–16–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2310]

Process To Request a Review of Food and Drug Administration's Decision Not To Issue Certain Export Certificates for Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices; Draft Guidance for Industry and Food and Drug Administration Staff.'' FDA is issuing this draft guidance to comply with changes to the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the FDA Reauthorization Act of 2017 (FDARA), to specify the process afforded to persons denied a Certificate to Foreign Government (CFG) for a device. This draft guidance describes the information that the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) will provide to a person whose request for a CFG for a device is denied, and the process for seeking review of such a denial. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by October 16, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–2310 for ''Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices; Draft Guidance for Industry and Food and Drug Administration Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9